Indiana State Department of Health
An Equal Opportunity Employer

Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

DATE: October 27, 2014

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: Laurie Kidwell, RRT Supervisor
Food Protection Program

SUBJECT: Baxter International Inc. – RECALL [Drug]

AFFECTED PRODUCT: **INTRAVIA containers**

SUMMARY: **Unclassified Recall; The recall is due to due to complaints received for particulate matter found inside the fluid path.**

INTRAVIA containers are empty plastic containers with PVC ports and a sterile fluid path. The recalled lots are INTRAVIA Container, 150 mL Capacity, Lot Number UR13D15112, Product Code 2B8011, distributed to customers between April 26, 2013 and June 20, 2013; and INTRAVIA Container, Empty 500 mL Capacity, Lot Number UR13K14095, Product Code 2B8013, distributed to customers between November 27, 2013 and March 10, 2014. Unaffected lot numbers can continue to be used according to the instructions for use.

The recalled product was distributed nationwide.

SUGGESTED ACTION: **For consumer inquiry only. Consumers with questions regarding this recall can call Baxter at 1-800-422-9837, Monday through Friday, between the hours of 8:00 a.m. and 5:00 p.m. Central Time, or e-mail Baxter at onebaxter@baxter.com.**

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Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Baxter Initiates Voluntary Recall of Two Lots of Intravia Containers in the U.S. and Canada

Contact:
Consumer:
1-800-422-9837

Media:
John O'Malley

Deborah Spak
1-224-948-5353
media@baxter.com

FOR IMMEDIATE RELEASE — October 22, 2014 — DEERFIELD, Ill. — Baxter International Inc. announced today it is voluntarily recalling two lots of INTRAVIA containers in the U.S. and Canada due to complaints received for particulate matter found inside the fluid path. Intravenous administration of a solution containing sterile particulate matter may lead to adverse health consequences. The extent and severity of harm depends on the size, number, and composition of the foreign material, and patient's underlying medical condition. There have been no reported adverse events associated with this issue to date.

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Baxter has notified customers, who are being directed not to use product from the recalled lots. Recalled product should be returned to Baxter for credit by contacting Baxter Healthcare Center for Service at 1-888-229-0001, Monday through Friday, between the hours of 7:00 a.m. and 6:00 p.m., Central Time. Unaffected lots of product are available for replacement.

Consumers with questions regarding this recall can call Baxter at 1-800-422-9837, Monday through Friday, between the hours of 8:00 a.m. and 5:00 p.m. Central Time, or e-mail Baxter at onebaxter@baxter.com. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to using this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report **Online**: www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax**: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

About Baxter

Baxter International Inc., through its subsidiaries, develops, manufactures and markets products that save and sustain the lives of people with hemophilia, immune disorders, cancer, infectious diseases, kidney disease, trauma and other chronic and acute medical conditions. As a global, diversified healthcare company, Baxter applies a unique combination of expertise in medical devices, pharmaceuticals and biotechnology to create products that advance patient care worldwide.

Baxter Initiates Voluntary Recall of Two Lots of Intravia Containers in the U.S. and

Canada
Photo

2B8013
Qty. 6

IntraVia™ Container, Empty
500 mL Capacity

2B8011

INTRAVIA Container
150 mL Capacity

STERILE NONPYROGENIC FLUID PATH USE ONLY WITH MEDICATIONS THAT ARE COMPATIBLE WITH EACH OTHER MIX THOROUGHLY CAUTIONS SQUEEZE AND INSPECT FILLED BAG DISCARD IF LEAKS ARE FOUND MUST NOT BE USED IN SERIES CONNECTIONS FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON ORDER OF A PHYSICIAN ADHERE TO STORAGE REQUIREMENTS OF ADDED MEDICATIONS SEE DIRECTIONS

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FOR PRODUCT INFORMATION 1-800-933-0303

Baxter

BAXTER HEALTHCARE CORPORATION
DEERFIELD IL 60015 USA

MADE IN USA